

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹—Continued

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
330.14(f) and (i); Submission of safety and effectiveness data, including data and information listed in 330.10(a)(2), a listing of all serious adverse drug experiences that may have occurred (330.14(f)(2)), and an official or proposed compendial monograph (330.14(i)).					
330.14(j) and (k); Submitter correspondence with FDA.					

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden reflects time needed for submitting applications, followup submissions of safety and efficacy data, and potential correspondence from submitters to FDA after a TEA has been submitted (*e.g.*, requests for an informal conference, signed statements that the submission is complete, requests for FDA to withdraw TEA consideration). The burden we attribute to reporting activities is assumed to be distributed among the individual elements and averaged among respondents.

Based on a recent review of the information collection and submissions of TEAs since our last request for OMB approval, we have made no adjustments to the currently approved burden estimates.

Dated: August 3, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–16922 Filed 8–7–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3107]

Pilot Program for Cosmetic Product Facility Registration and Listing Electronic Submissions User Acceptance Testing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Office of Cosmetics and Colors (OCAC) and the Office of the Chief Scientist (OCS) in the Food and Drug Administration (FDA, Agency, or we) are soliciting applications from members of the cosmetic product industry interested in participating in a voluntary pilot program to conduct user acceptance testing to help OCAC and OCS evaluate a potential new electronic submissions portal for cosmetic product

facility registration and listing. This electronic submission portal is being implemented pursuant to the Modernization of Cosmetics Regulation Act of 2022 (MoCRA). OCAC and OCS plan to accept up to nine participants for the pilot program. The pilot program is intended to provide OCAC and OCS input to inform evaluation of this new electronic submission portal.

DATES: Interested parties should submit an electronic application to participate in this pilot program by August 22, 2023. We plan to conduct pilot testing beginning on or about September 15, 2023. See section III of this document for information on applying for participation.

ADDRESSES: If you are interested in participating in this pilot program, please submit an electronic application to eRLC.testing@fda.hhs.gov.

FOR FURTHER INFORMATION CONTACT:

Jennifer Ross, Office of the Chief Scientist, Food and Drug Administration, 301–796–4880 (this is not a toll-free number), email: eRLC.testing@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On December 29, 2022, the President signed the Consolidated Appropriations Act, 2023 (Pub. L. 117–328) into law, which included MoCRA. Among other provisions, MoCRA added section 607 to the Federal Food, Drug, and Cosmetic Act (FD&C Act), establishing requirements for cosmetic product facility registration and cosmetic product listing.

Section 607(a) of the FD&C Act requires every person that owns or operates a facility that engages in the manufacturing or processing of a cosmetic product for distribution in the United States to register each facility with FDA no later than 1 year after the date of enactment. In addition to the registration requirements, section 607(c) of the FD&C Act requires that for each cosmetic product, the responsible

person submit to FDA “a cosmetic product listing.” Certain small businesses, as defined in section 612 of the FD&C Act, are exempt from the registration and listing requirements.

FDA previously had a voluntary cosmetics registration program (see 21 CFR parts 710 and 720). Because the information in the voluntary cosmetics registration program differs from the information required to be submitted under MoCRA, FDA does not consider previous submissions to the voluntary cosmetics registration program to satisfy the registration and listing mandated by MoCRA. Accordingly, FDA ended its voluntary registration program as of March 27, 2023, while we work toward establishing a new system, and information in the voluntary cosmetics registration program will not be transferred to this new system.

While electronic submission of registration and listing information is not required, FDA is strongly encouraging electronic submission to facilitate efficiency and timeliness of data submission and management by FDA. To that end, FDA will make an electronic portal available to streamline the data entry process for registration and product listing. Consequently, OCAC and OCS are announcing a pilot program to test the functionality and usability of the new electronic submission process.

II. Pilot Program Participation

The pilot program to evaluate the cosmetic product facility registration and listing electronic submission processes is to begin on or about September 15, 2023, and last approximately 2 weeks. FDA plans to select up to nine participants who represent a broad spectrum representation of the cosmetic product industry. Pilot program participants will receive training and may be asked to submit simulated regulatory submissions and/or information for their cosmetic products. During the pilot program, staff will be available to

address questions or concerns that may arise. Pilot program participants will also be asked to provide written and verbal feedback during their training and after they submit the simulated registration and listing information. This feedback will assist OCAC and OCS in ensuring the electronic submission portal is usable and functional to ensure industry will be able to meet its statutory obligations. OCAC and OCS estimate that each individual participant's involvement may require about 8 hours over the 2-week period. OCAC and OCS are soliciting applications from members of the cosmetic product industry who will be required to register their facilities and list their products, such as cosmetic product manufacturers, as well as entities that may act as authorized agents for manufacturers. At its discretion, OCAC and OCS may withdraw a participant from the pilot program for not completing the requested activities within requested timeframes.

None of the information submitted during the pilot will fulfill a participant's registration and listing responsibilities pursuant to MoCRA. Participants will need to submit their information in the electronic registration and listing system once it is available for submissions or through a paper form to fulfill their registration and listing responsibilities pursuant to MoCRA.

Entities that may be eligible to participate in this voluntary pilot program for cosmetic product facility registration and listing are limited to those firms following the procedures set out in section III. and that also meet the two selection criteria that follow:

1. required to submit cosmetic product facility registration and listing information to FDA pursuant to MoCRA by December 29, 2023; and,
2. willing to provide feedback on the cosmetic product facility registration and listing electronic submission process.

III. Applications for Participation

To be considered to participate in the pilot program, entities should submit a statement of interest for participation to eRLC.testing@fda.hhs.gov. The statement of interest should include the following information: company and contact name, contact phone number, and contact email address, size of the company (*i.e.*, number of personnel and the approximate amount of revenue per year), agreement to the selection criteria in section II of this document, as well as the number of cosmetic product(s) and a description of the cosmetic

product(s) intended to be submitted in the pilot program in enough detail to verify that the cosmetic product(s) are not drug product(s). A firm can choose to submit information for a subset of their products rather than all their products in the pilot program.

Additionally, although not required for consideration, FDA is interested in whether you are a manufacturer or may act as an authorized agent, and whether you have previously submitted registration and listing information to the Agency for any regulated product. Once statements of interest for participation in the pilot are received, FDA will contact interested applicants to confirm selection for the pilot program. FDA will not notify interested applicants who are not selected for the pilot program. FDA will select no more than nine participants, who best meet the selection criteria and who reflect a broad spectrum of cosmetic product manufacturers and processors, including companies that range in size and develop a range of products, or are an authorized agent. In the event a large number of submissions are received, FDA may only review a small number of submissions in order to identify nine (or fewer) for the pilot program.

Dated: August 2, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–16772 Filed 8–7–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–1157]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Generic Clearance for Qualitative Data To Support Social and Behavioral Research for Food, Dietary Supplements, Cosmetics, and Animal Food and Feed

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Submit written comments (including recommendations) on the

collection of information by September 7, 2023.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910–0891. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Generic Clearance for Qualitative Data To Support Social and Behavioral Research for Food, Dietary Supplements, Cosmetics, and Animal Food and Feed

OMB Control Number 0910–0891—Extension

OMB's Office of Information and Regulatory Affairs has issued memoranda that provides an overview of administrative flexibilities available to assist Agencies in complying with their statutory obligations under the PRA. Among these flexibilities is use of a generic clearance for certain information collection activities. A generic clearance may be appropriate when (1) the need for the data collection can be evaluated in advance, as part of the review of the proposed plan, but (2) the Agency cannot determine the details of the specific individual collections until a later time. Generic clearances cover collections that are voluntary, low-burden, and uncontroversial.

This generic clearance supports research intended to help the Center for Food Safety and Applied Nutrition understand stakeholders' perceptions, attitudes, motivations, and behaviors. To ensure that communications activities have the highest effect, we will conduct research and studies relating to the control and prevention of disease and the safety and health of the public. FDA is requesting OMB approval for the use of this generic collection of information that allows